FEB 2 4 2000

## 510(k) SUMMARY

This summary of 510(k) Safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is:_____.

### 1. Submitter's Identification :

Optimal Imaging Systems Inc.
9344 N.W. 13th Street, Suite 200
Miami, Florida 33172
Contact Person : Mr. Jorge Millan, MSEE

Date Summary Prepared: Tuesday, January 04, 2000

### 2. Name of the Device :

OIS-STAND ALONE Diagnostic Ultrasound System

### 3. Predicate Device Information :

1. **Aloka Co.**
   Model SSD-1700 K963616

2. **Diasonics Ultrasound**

| | | |
|---|---|---|
| Models | Synergy | K935024 |
| | CFM800 | K924079 |
| | EchoPac | K962662 |

3. **Perception Inc.**

| | | |
|---|---|---|
| Model | GPS-6TBMD | K981834 |
| Model | GPS-XYZ | K972192 |

4. **Pie Medical**

| | | |
|---|---|---|
| Model | Ultrasound Scanner #1150 | K900469 |

5. **International Ultrasound Co.**

| | | |
|---|---|---|
| Model | HRI 2000 | K961229 |

## 4. Device Description :

### General Description

The OIS-STAND ALONE Ultrasound System is a real time, two dimensional, mechanical sector and electronic array diagnostic ultrasound and pulsed Doppler imaging system which produces diagnostic ultrasonic images and blood flow spectral analysis through user friendly operation.

The following intended uses are identified for the transducer applications: General Radiology, Urology, Abdominal, Cardiac, Trans-vaginal, Trans-rectal, Vascular, Small Organs, Breast, Thyroid, Fetal Imaging and Musculo-Skeletal (conventional) with the use of ultrasonic probes from 3.0-12.5 MHz. There are no transcranial applications for this device.

User interface is via an alphanumeric keypad with incorporated trackball. The OIS-STAND ALONE Diagnostic Ultrasound System may be operated in M /B /D modes of inspection. The OIS-STAND ALONE Diagnostic Ultrasound System supports M, B, M&B, Dual B, Quad B, D and D/B, display modes.

All probes currently intended for use with the OIS-STAND ALONE Diagnostic Ultrasound System are either mechanical sector devices or electronic linear and curve array, and make use of a fluid filled design. Transducer parameters are summarized in the following table:

| App/Transducr Freq(MHz) | GP-3.0 2.8 | CA-3.5 3.5 | EV-6.5 6.5 | ER-6.5 6.5 | LA-7.5 6.5 | PV-12.5 12.5 |
|---|---|---|---|---|---|---|
| Abdominal | M/B/PWD | B/PWD | | | | |
| Cardiac | M/B/PWD | B/PWD | | | | |
| Vascular | | | | | M/B/PWD | M/B |
| Trans-rect | | | | B | | |
| Trans-vag | | | M/B | | | |
| Small Organ Breast, Thyroid, Testes, Musculo-skeletal | M/B/PWD | B/PWD | | | B | B |
| Fetal | M/B | B | M/B | | | |

## 5. Intended Use:

See Attachment.

**6. Comparison to Predicate Devices:**

We believe the OIS-STAND ALONE Diagnostic Ultrasound System to be substantially equivalent to ultrasound devices currently in commercial distribution in the U.S. A table of comparison outlining similarities and differences between the OIS-STAND ALONE Diagnostic Ultrasound System and predicate devices is attached to this summary.

**7. Discussion on Non-Clinical Test Performed for Determination of Substantial Equivalence are as Follows:**

The OIS-STAND ALONE Diagnostic Ultrasound System is similar to the Perception Inc. GPS-6TBMD Diagnostic Ultrasound System, 510(k) #K981834. The ultrasonic electronic system and transducers conform to the same specifications as the GPS-6TBMD system and transducers, and they are acquired from the same manufacturers. There is no distinction on the ultrasonic electronic system and transducers between the GPS-6TBMD and the IOS-STAND ALONE besides labeling. We believe the GPS-6TBMD test results can be applied to the OIS-STAND ALONE system for determining substantially equivalence in this respect.

**8. Discussion of Clinical Test Performed:**

**Not Applicable**

**9. Conclusions:**

The OIS-STAND ALONE Diagnostic Ultrasound System has the same intended use as a combination of all cited predicates. All non-clinical testing and biocompatibility testing revealed no new questions of safety or effectiveness. This, when compared to the predicate devices, the OIS-STAND ALONE Diagnostic Ultrasound System does not incorporated any significant changes in intended use, method of operations, material or design that could affect safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 24 2000

Jorge Millan
Official Correspondent
Optical Imaging Systems, Inc.
9344 N.W. 13th Street
Suite 200
Miami, FL 33172

Re: K000034
OIS-STAND-ALONE - Diagnostic Ultrasound System
Regulatory Class: II
21 CFR892.1550/Procode: 90 IYN
Dated: January 5, 2000
Received: January 6, 2000

Dear Mr. Millian

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the OIS-STAND-ALONE - Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

GP-3.0 MHz Mechanical Sector
CA-3.5 MHz Curved Array
EV-6.5 MHz Curved Array
ER-6.5 MHz Mechanical Sector
LA-7.5 MHz Linear Array
PV-12.5 MHz Mechanical Sector

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Please be advised that the determination above is based on the fact that no medical devices have been demonstrated to be safe and effective for in vitro fertilization or percutaneous umbilical blood sampling, nor have any devices been marketed for these uses in interstate commerce prior to May 28, 1976, or reclassified into class I (General Controls) or class II (Special Controls). FDA considers devices specifically intended for in vitro fertilization and percutaneous umbilical blood sampling to be investigational, and subject to the provision of the investigational device exemptions (IDE) regulations, 21 CFR, Part 812. Therefore, your product labeling must be consistent with FDA's position on this use.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Paul M. Gammell, Ph.D. at (301) 594-1212.

Sincerely yours,

for Daniel G. Schultz

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

**510(k) Number (if known):** K000034

**Device Name :** OIS-STAND ALONE - Diagnostic Ultrasound System

**Indications For Use:**

The OIS-STAND ALONE Diagnostic Ultrasound System device is a diagnostic ultrasound system, which produces two-dimensional diagnostic ultrasonic images and spectral Doppler analysis. The following intended uses are identified for the transducer applications: General Radiology, Urology, Abdominal, Cardiac, Trans-vaginal, Trans-rectal, Vascular, Small Organs, Breast, Thyroid, Fetal Imaging and Musculo Skeletal (conventional) with the use of ultrasonic probes from 3.0 to 12.5. There are no transcranial applications for this device.

**(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IFNEEDED)**

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

**Prescription Use** ✓ **OR** **Over-The-Counter Use** _____
**(Per 21 CFR 801.109)**

**(Optional Format 1-2-96)**

David A. Segerson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K000034

K000034

## Diagnostic Ultrasound Indications for Use Form

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

### GP-3.0 MHz Mechanical Sector-Transducer

| | Mode of Operations | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Clinical Application** | **A** | **B** | **M** | **PWD** | **CWD** | **Color Doppler** | **Amplitude Doppler** | **Color Velocity Imaging** | **Combined (specify)** | **Other (specify)** |
| Ophthalmic | | | | | | | | | | |
| Fetal | | X | X | | | | | | M+ ref B | |
| Abdominal | | X | X | X | | | | | M+ ref B<br>PWD + ref B | |
| Intraoperative(specify) | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ (specify) | | X | X | X | | | | | M+ ref B<br>PWD + ref B | |
| Neonathal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | X | X | X | | | | | M+ ref B<br>PWD + ref B | |
| Transesophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | X | X | X | | | | | M+ ref B<br>PWD + ref B | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) | | | | | | | | | | |

N= new indication; P= previously cleared by FDA; E= Added under Appendix E

Additional Comments: Small Organs: Breast, Thyroid, Testes.

Prescription Use ✓
(Per 21 CFR 801.109)

David A. Segares
(Division Sign-Off)
Division of Reproductive
and Radiological Devices

510(k) Number K000034

K000034

## Diagnostic Ultrasound Indications for Use Form

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

### CA-3.5 MHz Curve Array-Transducer

| | Mode of Operations | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Clinical Application** | **A** | **B** | **M** | **PWD** | **CWD** | **Color Doppler** | **Amplitude Doppler** | **Color Velocity Imaging** | **Combined (specify)** | **Other (specify)** |
| Ophthalmic | | | | | | | | | | |
| Fetal | | X | | | | | | | | |
| Abdominal | | X | | X | | | | | PWD+ ref B | |
| Intraoperative(specify) | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ (specify) | | X | | X | | | | | PWD+ ref B | |
| Neonathal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | X | X | X | | | | | M+ ref B<br>PWD+ ref B | |
| Transesophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | X | | X | | | | | PWD+ ref B | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) | | | | | | | | | | |

N= new indication; P= previously cleared by FDA; E= Added under Appendix E

Additional Comments: Small Organs: Breast, Thyroid, Testes.

Prescription Use ✓
(Per 21 CFR 801.109)

David C. Segroves
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K000034

K000034

## Diagnostic Ultrasound Indications for Use Form

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

### ER-6.5 MHz Mechanical-Transducer

| | Mode of Operations | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Clinical Application** | **A** | **B** | **M** | **PWD** | **CWD** | **Color Doppler** | **Amplitude Doppler** | **Color Velocity Imaging** | **Combined (specify)** | **Other (specify)** |
| Ophthalmic | | | | | | | | | | |
| Fetal | | | | | | | | | | |
| Abdominal | | | | | | | | | | |
| Intraoperative(specify) | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ (specify) | | | | | | | | | | |
| Neonathal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Transesophageal | | | | | | | | | | |
| Transrectal | | X | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) | | | | | | | | | | |

N= new indication; P= previously cleared by FDA; E= Added under Appendix E

Additional Comments: NONE

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

Prescription Use ✓
(Per 21 CFR 801.109)

510(k) Number K000034

K000034

## Diagnostic Ultrasound Indications for Use Form

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

### EV-6.5 MHz Curve Array-Transducer

| | Mode of Operations | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Clinical Application** | **A** | **B** | **M** | **PWD** | **CWD** | **Color Doppler** | **Amplitude Doppler** | **Color Velocity Imaging** | **Combined (specify)** | **Other (specify)** |
| Ophthalmic | | | | | | | | | | |
| Fetal | | X | X | | | | | | M+ ref B | |
| Abdominal | | | | | | | | | | |
| Intraoperative(specify) | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ (specify) | | | | | | | | | | |
| Neonathal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Transesophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | X | X | | | | | | M+ ref B | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) | | | | | | | | | | |

N= new indication; P= previously cleared by FDA; E= Added under Appendix E

Additional Comments: NONE

Prescription Use ✓
(Per 21 CFR 801.109)

David A. Seguin
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K000034

K000034

## Diagnostic Ultrasound Indications for Use Form

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

### LA-7.5 MHz Linear Array-Transducer

| | Mode of Operations | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Clinical Application** | **A** | **B** | **M** | **PWD** | **CWD** | **Color Doppler** | **Amplitude Doppler** | **Color Velocity Imaging** | **Combined (specify)** | **Other (specify)** |
| Ophthalmic | | | | | | | | | | |
| Fetal | | | | | | | | | | |
| Abdominal | | | | | | | | | | |
| Intraoperative(specify) | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ (specify) | | X | | | | | | | | |
| Neonathal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Transesophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral Vascular | | X | X | X | | | | | M+ ref B PWD+ ref B | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) | | | | | | | | | | |

N= new indication; P= previously cleared by FDA; E= Added under Appendix E

Additional Comments: Small Organs: Breast, Thyroid, Testes.

David A. Seguss

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K000034

Prescription Use ✓
(Per 21 CFR 801.109)

K000034

## Diagnostic Ultrasound Indications for Use Form

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

### PV-12.5 MHz Mechanical Sector-Transducer

| | Mode of Operations | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Clinical Application** | **A** | **B** | **M** | **PWD** | **CWD** | **Color Doppler** | **Amplitude Doppler** | **Color Velocity Imaging** | **Combined (specify)** | **Other (specify)** |
| Ophthalmic | | | | | | | | | | |
| Fetal | | | | | | | | | | |
| Abdominal | | | | | | | | | | |
| Intraoperative(specify) | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ (specify) | | X | | | | | | | | |
| Neonathal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Transesophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral Vascular | | X | X | | | | | | M + ref B | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) | | | | | | | | | | |

N= new indication; P= previously cleared by FDA; E= Added under Appendix E

Additional Comments: Small Organs: Breast, Thyroid, Testes.

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

Prescription Use ✓
(Per 21 CFR 801.109)

510(k) Number K000034

K000034

## Diagnostic Ultrasound Indications for Use Form

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

### OIS-STAND ALONE – ULTRASOUND SYSTEM

| | Mode of Operations | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Clinical Application** | **A** | **B** | **M** | **PWD** | **CWD** | **Color Doppler** | **Amplitude Doppler** | **Color Velocity Imaging** | **Combined (specify)** | **Other (specify)** |
| Ophthalmic | | | | | | | | | | |
| Fetal | | X | X | | | | | | M+ref B | |
| Abdominal | | X | X | X | | | | | M+ref B PWD + ref B | |
| Intraoperative(specify) | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ (specify) | | X | X | X | | | | | M+ref B PWD + ref B | |
| Neonathal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | X | X | X | | | | | M+ref B PWD + ref B | |
| Transesophageal | | | | | | | | | | |
| Transrectal | | X | | | | | | | | |
| Transvaginal | | X | X | | | | | | M+ref B | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral Vascular | | X | X | X | | | | | M+ref B PWD + ref B | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | X | X | X | | | | | M+ref B PWD + ref B | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) | | | | | | | | | | |

N= new indication; P= previously cleared by FDA; E= Added under Appendix E

Additional Comments: Small Organs: Breast, Thyroid, Testes.

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

Prescription Use ✓
(Per 21 CFR 801.109)

510(k) Number K000034